

REMARKS

1. Claims Deemed Allowable; Overview of Claim Amendments

At page 6, the Examiner states

Claims 9, 42-46 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note that claim 48 is additionally rejected under 35 USC 112, 1st paragraph (New Matter).

We have amended claim 4 to incorporate the limitation of claim 42, and cancelled 42 as redundant. The amendment of claim 4 renders it ripe for allowance, for the same reason that claim 42 was deemed allowable. And it also overcomes the prior art rejections against claims dependent on 4.

Claim 4, as presented, recites "A purified retroviral envelope polypeptide...." We amended claim 4 to recite "A purified or non-naturally occurring polypeptide comprising an amino acid sequence which is at least 96% identical to the retroviral envelope polypeptide amino acid sequence shown in SEQ ID NO:2...."

The principal reason for the amendment was to avoid any doubt as whether the preamble language would include polypeptides that were non-naturally occurring mutants of the SID2 polypeptide. Such mutants were clearly contemplated, see P8, L2-P9, L26 and clause (b) of claim 4. Polypeptides per se were disclosed at P3, L25.

A further reason was to avoid any issue as to whether certain of the withdrawn claims were properly dependent on claim 4, i.e., in a virus claim, is it proper to speak of the virus as comprising a purified polypeptide? Nonetheless, if the "non-naturally occurring mutant" language is problematic, we are willing to delete it if it would result in allowance.

Applicants had contemplated both (1) polypeptides having an amino acid sequence at least 94% identical to SEQ ID NO:2, and

(2) "fragments" of such sequences that were at least 94% identical to a fragment (presumably of equal length) of SEQ ID NO:2. See P14, L19-24. Nearly identical wording is used at P6, L11-16, with subranges (including at least 96%) recited.

In view of the art rejection against claim 4, we have deleted the explicit reference to "fragments". However, we believe that some fragments are still covered because they are at least 94% identical to SEQ ID NO:2 rather than to merely a fragment of SEQ ID NO:2. To avoid dispute as to how percentage identity is calculated for the purpose of the present claim, claim 4 now states "with percentage identity calculated relative to the full length of SEQ ID NO:2", with basis at P6, L35. This is without prejudice to presentation, in a continuation application, of claims to fragments in which the percentage identity is calculated only over the length of the fragment.

We have amended clause (b) to clarify that the term "VR3 region" refers to a region of SEQ ID NO:2 (cp. P7, L22-35), and thus that the recited substitution creates a difference between the claimed polypeptide and SID2, and also that the requirement of a VR3 region substitution applies only to polypeptides with activity (b). Otherwise, claim 4 would be inconsistent with dependent claims 46 and 48. Of course, polypeptides with activity (a) might optionally possess such a mutation.

We have rewritten claim 48 in independent form. It parallels amended claim 4 except that 95% was not changed to 96% in view of the limitation unique to 48, quoted below.

We understand claim 48 to have been deemed allowable if the written description rejection (OA p. 2) is overcome.

Claim 48 as examined was directed to:

The polypeptide of claim 4 which comprises  
a subsequence identical to the VR3 region  
(amino acids 199-213) of SEQ ID NO:2.

We believe that there is ample basis for this limitation in the description of the VR3 region, amino acids 199-213, in Fig. 2 and at page 7, lines 22-35 of the specification:

In a sequence alignment between SL3-2 and MCF-247, three regions display differences in the amino acid sequence, as described in example 3 and figure 1 and 2. Two of these regions correspond to parts of the variable VRA and VRB regions, whereas the third is a 15 amino acids long stretch upstream of the proline rich region. The present inventors have named this region VR3.

#### VR3 region

Further, a sequence alignment of MLVs from different sub-families show conserved amino acids at positions 203-208 WGLRLY and at positions 214-215 DP based on SL3-2 sequence, thus defining a 13 amino acid stretch of SEQ ID NO:2.

In the present context, the term "VR3 region" comprises all of the amino acids found between the residue found at two positions after the conserved tryptophan 197 and the residue before the conserved aspartic acid 214 (according to the sequence shown in SEQ ID NO:2) including these two positions.

Since the polypeptide of claim 48 has a VR3 region identical to that of SID2, recitation of activity (b) (and the associated VR3 substitution) is inappropriate.

Claim 9 has also been rewritten as an independent claim. With respect to claim 9, we believe that the office action summary page erroneously lists claim 9 as rejected ("6-10"). Not only does this contradict the listing of allowable claims on page 6, claim 9 is not referred to in the actual rejections on pp. 2-5, and rejection of claim 9 is difficult to reconcile with the prior rejection (March 25, 2008) which indicated on page 11 that claim 9 defined "allowable matter"<sup>1</sup>.

Claim 9 requires that the polypeptide differ from SID2 at least by replacement of Arg-212 with methionine. In the alignment of SID2 with Sijt's sequence set forth in the March 25, 2008 action page 7, the aligned Sijt's residue is Glycine. Hence

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<sup>1</sup> Despite a 112/2 rejection of claim 9 stated on page 4.

Sijts does not anticipate claim 9. Nor does it render claim 9 obvious, because Sijts fails to provide any motivation for replacing Gly-112 with methionine. Hence claim 9 is not amended to recite at least 96% identity.

Since claim 9 recites the aforementioned substitution, it was unnecessary to repeat the broader claim 4 requirement of a VR3 region mutation.

New claim 49 is similar to 9 but dependent on 4.

## **2. Prior Art Issues**

2.1. The rejection of claims 4, 6, 8 and 47 as anticipated by Sijts with evidence from Yang is overcome by the amendment of claim 4 to incorporate the 96% identity limitation of claim 42, deemed allowable at page 6 of the action.

Claims 6, 8 and 47 are allowable by virtue of their dependency on amended claim 4.

2.2. Claims 4, 7 and 10 stand rejected as anticipated by or obvious over Sijts. Since claim 4 has been amended to incorporate the limitation of claim 42, which was not deemed obvious over Sijts, it follows that the obviousness rejection is overcome.

## **3. Possible Rejoinder of Withdrawn Claims**

3.1. Claims 11-16, 19, 21, 22, 24 have a combination/subcombination relationship to claim 4. Since the subcombination claim has been deemed allowable, these dependent combination claims should be rejoined. See PCT Administrative Instructions, Annex B, paragraph (c)(i).

3.2. The species restriction between the envelope peptide (claim 4) and the nucleic acid (claim 17) should be withdrawn because there is a corresponding technical relationship under the PCT International Search and Preliminary Examination Guidelines, section 10.59, example 39, between a protein and the nucleic acid encoding that protein.

For similar reasons, claim 29, to the packaging cell

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construct, should be rejoined.

3.3. The dependent method claims 30-37, 39, and 40 should be rejoined in accordance with MPEP 821.04, see section 16 of the October 5, 2007 restriction.

3.4. Applicants are willing to instead cancel withdrawn claims that, if rejoined, would be rejected.

3.5. Withdrawn claim 18 has been cancelled.

Respectfully submitted,

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